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10/812,363	03/30/2004	Rajender Singh Sangwan	033166-025	4114

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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 10/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/812,363

Applicant(s)

SANGWAN ET AL.

Examiner

Christopher R. Tate

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### DETAILED ACTION

Claims 1-14 are presented for examination on the merits.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite for the following reasons:

- The preamble phrase "process for isolation of withaferin-A from plant materials and products therefrom" causes confusion and unclarity with respect to if the claims are solely defining a preparatory process or if they are also attempting to define one or more products produced therefrom (which would be improper within this method claim). It is, therefore, suggested that the phrase "and products therefrom" be omitted from the preamble claim 1. In addition, the preamble phrase "comprising steps of" is grammatically incorrect and somewhat confusing. It is suggested that this phrase be expanded to recite --comprising the steps of-- or similar phraseology.
- In step (i), the singular phrase "the said plant material" lacks antecedent basis (please note the preamble phrase recites the plural phrase "plant materials").

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- It is totally unclear as to what the terms "withanolidal" [recited in steps (ii) and (iii)] and "withanolidal aglycones" are actually defining - i.e., an extensive search of the US Patent databases as well as an extensive STN search including of the Registry File failed to uncover either of these terms (i.e., "withanolidal" or "withanolidal"). Accordingly, it is unknown what these art-obscure terms are attempting to define within the claimed method. In addition, is the phrase "to obtain withanolidal" (step ii) attempting to define obtaining some type of purified/isolated compound? If so, it would not seem feasible that by extracting and defatting the plant material via the first two steps of claim 1 would provide such a purified/isolated compound.
- In step (iii), the phrase "a chloroform" is unclear because this would imply that more than one chloroform exists. However, "chloroform", by definition, constitutes only one chemical entity: (CHCl<sub>3</sub>) - also known as trichloromethane. Accordingly, it is suggested that the term "a" be omitted from this phrase.
- In step (iv), the phrase "extract as obtained in step (iii)". There is insufficient antecedent basis for this limitation in the claim [please note that there is no recitation of an extract being obtained in step (iii)].
- The recited limitations of final step (iv) appear to be incomplete since it would not appear to result in the isolation of the compound withaferin-A - i.e., "dissolving extract as obtained in step (iii) in methanol" would not appear to actually result in the isolation of the compound withaferin-A, but instead would result in a methanolic solution apparently containing the claimed compound. Accordingly, claim 1 is deemed incomplete for omitting essential steps (i.e., the essential step(s) necessary to actually isolate the compound withaferin-A from the claimed plant material (see, e.g., MPEP § 2172.01).

Claim 2 is rendered vague and indefinite by the phrase "wherein the extraction solvent consists of water and alcohol in the ratio varying in the range of 100 % to 0 % because the maximum (100%) and minimum (0%) amounts instantly claimed would exclude water and alcohol, respectively (yet the claim defines the extraction solvent as consisting of both).

Many of the dependent claim recitations are generally narrative in nature, are very unclear and/or are very confusing and, thus, do not adequately define and/or delineate the metes and bounds of the claim language (they fail to conform with current U.S. practice). They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. Examples of narrative, unclear and/or confusing phrases include:

- In claim 3, the phrase "wherein the said material is selected from ... dry and fresh biomass of plant / plant material to avoid desiccation/ air drying induced variability of withanolidal contents (what is the attempting to define and, also - again - what is the meaning of "withanolidal"?).
- In claim 4, the phrase "prior washing of the dry material with water and the prior water extraction, affords two fold improvement in withaferin-A yield compared to approach of alcohol or aquated alcohol extraction (what is this narrative, grammatically-confusing phrase attempting to define; also - what does "aquated" mean?).
- In claim 7, the phrase "the high resolution system ... 70 : 4 : 8 : 24" (what is this narrative, grammatically-confusing phrase attempting to define? / further, there does not appear to be antecedent basis for the limitations within this phrase). In addition, the phrase "in claims 1, 2, 9, and 10" (line 1) is an improperly formatted multiple dependent claim. The term "and" therein should be replaced with --or--.

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- In claims 8-11, starting at line 1 of each, the phrases "wherein percentage of water in the said extraction solvent system" (claim 8); "wherein percentage of water in the extraction solvent ..." (claim 9); "wherein selecting alcoholic solvent from a water-miscible group comprising methanol ..." (claim 10); and "polar withanolidal phytochemicals" (claim 11) lack adequate antecedent basis (some of these overall phrases are also unclear and indefinite; further - again - it is unclear as to the meaning of "withanolidal").

- In claim 12, the phrase "wherein the process provides quantitative profiling of withaferin levels for standardization of botanicals, herbal products, phytomedicines, nutraceuticals and food supplements (what is this narrative phrase attempting to actually define?).

- In claim 13, the phrase "but not limited to, such as (as?) powders, pastes, saps, capsules, tablets, syrups, etc." A broad range or limitation followed by linking terms (preferably, for instance, such as, but not limited to) and a narrow range or limitation within the broad range or limitation is considered indefinite since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired - see MPEP 2173.05(c) for additional information (Also, how many powders, pastes, saps, etc. are the claims attempting to define? Also, the ambiguous ending term "etc" is indefinite. It is suggested, that this claim be amended to conform to standard U.S. practice: e.g., --selected from the group consisting of a powder, a paste, sap, a capsule, a tablet, and a syrup-- as recited in claim 13 of co-related Application No. 10/822,858).

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

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***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-14 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-17 of copending Application No. 10/822,858 (please note that the claims are identical other than that instant claim 7 is a multiple dependent claim, whereas claim 7 of US Appl. '858 separates the claim 7 limitations into claims 7 and 15-17; further, instant claim 13 is essentially identical claim 13 of US Appl. '858 - i.e., instant claim 13 merely recites improper linking language and plural recitations (as discussed above under USC 112, second paragraph) but still conveys the same limitations therein. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nair et al. (US 2004/0096524) and Dinan et al. (J. Chromatogr. A, 2001), in view of Kaufmann et al. (Chromatographia, 2001).

Although difficult to interpret (see USC 112, second paragraph rejections discussed *supra*), a process for isolating withaferin-A from plant material via extracting the plant material with an extraction solvent, partitioning the extract with n-hexane followed by chromatographic separation (to obtain withanolide?), portioning out certain constituents (withanolide aglycones?) with chloroform, evaporating the chloroform, and dissolving the resulting extract in methanol to obtain withaferin-A is apparently claimed.

Nair et al. beneficially teach a method of extracting therapeutic, bioactive withanolides (including withaferin-A) from plant material (*Withania somifera* leaves - which Nair et al. teaches was identical to fresh harvested leaves - see paragraph [0033]) via extracting the plant material with an extraction solvent (including methanol and water) to form a crude plant material which is then exposed to (partitioned with) n-hexane (which would also intrinsically act as a defatting step) followed by chromatographic separation, then subsequently contacting the preparation with chloroform ( $\text{CHCl}_3$ ) and/or methanol (see, e.g., paragraphs [0046]-[0047]).

In a review article concerning the isolation of therapeutic, bioactive plant steroids such as withanolides (including withaferin-A) from plant material (such as *Withania* species), Dinan et al. beneficially teach various result-effective conventional working parameters (including various extraction/partitioning solvents) with respect to the efficient isolation of such plant steroids therefrom. Dinan et al. further disclose that withanolides (including withaferin-A) from such plant material are generally extracted from plant material with methanol or ethanol admixed with



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water, then partitioned against hexane (to remove pigment - which would also intrinsically act as a defatting step), whereby the desired withanolide(s) are separated via chromatographic steps such as thin layer chromatography (TLC) or high pressure liquid chromatography (HPLC).

Dinan et al. further disclose that chloroform ( $\text{CHCl}_3$ ) and methanol are frequently used for final purification of the desired withanolide(s) within such chromatographic procedures (see entire document including *Abstract*, *Introduction*, Figure 1, pages 107-108 under the heading *General purification strategy*, Tables 2-5, pages 118-119 - beginning with the heading *Withanolides*, and *Conclusions*).

Neither of the primary references expressly teach certain claim limitations - e.g., evaporating the chloroform therefrom and/or dissolving the evaporated extract in methanol.

Kaufman et al. beneficially teach the efficient extraction of withanolides (including withaferin-A) from plant material (such as leaves). Kaufman et al. advantageously disclose that such plant material can be extracted with various extraction solvents including methanol, water, or chloroform, as well as evaporating such solvents therefrom followed by dissolving the evaporated extract in methanol prior to performing high pressure liquid chromatography (see entire document including, e.g., *Summary*, *Introduction*, Figure 1, page 395 under the heading *Pressurised Solvent Extraction*, and *Conclusion*).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to isolate/provide withaferin-A (including within a methanolic preparation) via the (very unclear) steps instantly claimed - e.g., by extracting a suitable plant material with an extraction solvent (such as methanol and water), partitioning the extract with n-hexane followed by chromatographic separation (such as TLC and/or HPLC), contacting with

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chloroform, evaporating the chloroform, and dissolving the evaporated extract in methanol based upon the overall teachings provided by the cited references, as discussed above. The result-effective adjustment of particular conventional working conditions (e.g., determining suitable percentage ranges of water and/or methanol within such an extraction solvent; as well as performing such steps in a particular order\*) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

\*If necessary, please note that the selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results (In re Burhans, 69 USPQ 330; CCPA 1946) - see, e.g., MPEP 2144.04 (d)].

### **Conclusion**

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970.

The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher R. Tate  
Primary Examiner  
Art Unit 1655